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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-484]

Schedules of Controlled Substances: Extension of Temporary Placement of beta-Hydroxythiofentanyl in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary rule; temporary scheduling order; extension.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to extend the temporary schedule I status of beta-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) also known as *N*-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-*N*-phenylpropanamide including its isomers, esters, ethers, salts and salts of isomers, esters and ethers. The schedule I status of beta-hydroxythiofentanyl currently is in effect through May 12, 2018. This temporary order will extend the temporary scheduling of beta-hydroxythiofentanyl for one year, or until the permanent scheduling action for this substance is completed, whichever occurs first.

DATES: This temporary scheduling order, which extends the final order (81 FR 29492, May 12, 2016), is effective May 12, 2018 and expires on May 12, 2019. If this order is made permanent, the DEA will publish a document in the *Federal Register* on or before May 12, 2019.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

On May 12, 2016, the Acting Administrator of the Drug Enforcement Administration (DEA) published a final order in the *Federal Register* (81 FR 29492) temporarily placing beta-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) in schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). That final order was effective on the date of publication, and was based on findings by the Acting Administrator of the DEA that the temporary scheduling of beta-hydroxythiofentanyl was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), requires that the temporary control of this substance expires two years from the effective date of the scheduling order, or on May 12, 2018. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling¹ of that substance could be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his own motion, at the

¹ Though DEA has used the term “final order” with respect to temporary scheduling orders in the past, this notice adheres to the statutory language of 21 U.S.C. 811(h), which refers to a “temporary scheduling order.” No substantive change is intended.

request of the Secretary of Health and Human Services,² or on the petition of any interested party.

The Acting Administrator of the DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule beta-hydroxythiofentanyl. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for this substance. On December 8, 2016, the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for butyryl fentanyl and beta-hydroxythiofentanyl, and in accordance with 21 U.S.C. 811 (b) and (c). In a letter dated November 1, 2017, DEA notified HHS that it no longer required a scientific and medical evaluation for butyryl fentanyl because the Commission on Narcotic Drugs (CND), at its 60th session, added butyryl fentanyl to Schedule I of the Single Convention on Narcotic Drugs, 1961. On April 20, 2018, the DEA published a final scheduling order for butyryl fentanyl (83 FR17486) to meet international treaty obligations pursuant to 21 U.S.C. 811(d)(1).

Upon evaluating the scientific and medical evidence, on April 27, 2018, the HHS submitted to the Acting Administrator of the DEA its scientific and medical evaluation and scheduling recommendation for beta-hydroxythiofentanyl. Upon receipt of the scientific and medical evaluation and scheduling recommendation from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-

² Because the Secretary of the Department of Health and Human Services has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this temporary order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

factor analysis of the abuse potential of beta-hydroxythiofentanyl in accordance with 21 U.S.C. 811(c). The DEA published a notice of proposed rulemaking for the placement of beta-hydroxythiofentanyl in schedule I elsewhere in this issue of the *Federal Register*. If this order is made permanent, the DEA will publish a final rule in the *Federal Register*.

Pursuant to 21 U.S.C. 811(h)(2), the Acting Administrator of the DEA orders that the temporary scheduling of beta-hydroxythiofentanyl, including its isomers, esters and ethers and salts of isomers, esters, ethers, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

In accordance with this temporary scheduling order, the schedule I requirements for handling beta- hydroxythiofentanyl, including its isomers, esters and ethers and salts of isomers, esters, ethers, will remain in effect for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). The Attorney General may, by order, schedule a substance in schedule I on a temporary basis. *Id.* 21 U.S.C. 811(h) also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings to permanently schedule the substance, extend the temporary scheduling for up to one year.

To the extent that 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, the DEA believes that the notice and comment requirements of section 553 of

the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety. Further, the DEA believes that this order extending the temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, “any rule for which an agency for good cause finds that notice

and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to maintain the temporary placement of beta-hydroxythiofentanyl in schedule I because it poses a public health risk. The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. The DEA understands that the CSA frames temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly, and this extension of the temporary scheduling order continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to place this substance in schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order extending the temporary scheduling order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Dated: May 7, 2018

Robert W. Patterson,
Acting Administrator.

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